



Rev 2/06

1615

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application : Vladimir P. Torchilin et al.  
Application No. : 10/553,612  
Filed : October 18, 2005  
Confirmation No. : 1991  
For : MICELLE DELIVERY SYSTEM LOADED WITH A  
PHARMACEUTICAL AGENT  
Examiner : Unassigned  
Attorney's Docket : NU-604XX

TC Art Unit: 1615

\* \* \* \* \*  
I hereby certify that this correspondence is being deposited with the  
United States Postal Service as first class mail in an envelope  
addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box  
1450, Alexandria, VA 22313-1450 on May 18, 2007.

By: Holliday C. Heine  
Holliday C. Heine, Ph.D.  
Registration No. 34,346  
Attorney for Applicant(s)

\* \* \* \* \*

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

It is desired to cite for the record in this application the enclosed references listed on the attached copy of PTO Form #1449. The paragraph(s) marked below are applicable to this Information Disclosure Statement.

[ ] (1) Pursuant to 37 C.F.R. § 1.97(b)(1) and (2), the attached Information Disclosure Statement is being filed within three months of the filing date of the above identified national application or within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 of the above

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identified application. Accordingly, applicant(s) believes that no fee or statement under 37 C.F.R. § 1.97(e) is required.

- [X] (2) Pursuant to 37 C.F.R. § 1.97(b)(3), applicant(s) believes the attached Information Disclosure Statement is being filed before the mailing date of a first Office action on the merits. Accordingly, applicant(s) believes that no fee or statement under 37 C.F.R. § 1.97(e) is required.
- [ ] (3) Pursuant to 37 C.F.R. § 1.97(b)(4), applicant(s) believes the attached Information Disclosure Statement is being filed before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114. Accordingly, applicant(s) believes that no fee or statement under 37 C.F.R. § 1.97(e) is required.
- [ ] (4) Pursuant to 37 C.F.R. § 1.97(c), the attached Information Disclosure Statement is being filed before the mailing date of a final action or a notice of allowance and is accompanied by:  
[ ] a statement under 37 CFR § 1.97(e); or  
[ ] the fee set forth in § 1.17(p).

PETITION UNDER 37 CFR § 1.97(d)

- [ ] (5) Pursuant to 37 CFR § 1.97(d), applicant(s) hereby petitions the Commissioner to consider the attached Information Disclosure Statement which is being filed on or before payment of the issue fee. This petition is accompanied by a statement under 37 C.F.R. § 1.97(e) and the petition fee set forth in 37 C.F.R. § 1.17(p).

STATEMENT UNDER 37 C.F.R. § 1.97(e)(1)

- [ ] (6) The undersigned hereby states that each item of information contained in the attached Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

STATEMENT UNDER 37 C.F.R. § 1.97(e)(2)

- [ ] (7) The undersigned hereby states that no item of information contained in the attached Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the

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undersigned after making reasonable inquiry, no item of information contained in the attached Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Where the status of the application has changed, unknown to the applicant, such that the boxes checked are no longer applicable, the Commissioner is authorized to accept this submission with any additional fees required by that change charged to Deposit Account No. 23-0804.

The filing of this Information Disclosure Statement is not a representation by the undersigned as to personal knowledge of the contents of every word or phrase of the material enclosed or that reliance on other suitably trained professionals has not been made. The filing of this Information Disclosure Statement is not to be construed to be an admission that the information cited herewith is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that Applicant(s) is(are) unable to provide an affidavit under 37 CFR §1.131 swearing back of such information.

If a search report of a searching agency is enclosed identifying the nature of the relevance of each document, such a designation is deemed to satisfy 37 C.F.R. § 1.98(a)(3) even if in a foreign language because the codes are the same in all languages. However, applicant(s) does not necessarily adopt the position reflected by that report.

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The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 23-0804. Triplicate copies of this letter are enclosed.

Respectfully submitted,

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<b>U. S. DEPARTMENT OF COMMERCE (REV. 05/03) PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>				ATTY. DOCKET NO. NU-604XX	APPLICATION NO. 10/553,612	
				APPLICANT: Vladimir P. Torchilin et al.		
				FILING DATE October 18, 2005	TC ART UNIT 1615	
<b>U. S. PATENT DOCUMENTS</b>						
EXAMINER INITIAL	DOCUMENT NUMBER	PUBLICATION/ ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE
	US 6,217,886 B1	04/17/01	Önyüksel et al.	424	401	01/27/99
<b>FOREIGN PATENT DOCUMENTS</b>						
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES      NO
<b>OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)</b>						
	Gao et al., "Diacyllipid-Polymer Micelles as Nanocarriers for Poorly Soluble Anticancer Drugs", American Chemical Society, Nano Letters, Vol. 2, No. 9, pp. 979-982, 2002.					
	Iakoubov L.Z. & Torchilin V., "A novel class of antitumor antibodies: nucleosome-restricted antinuclear autoantibodies (ANA) from healthy aged nonautoimmune mice", Oncol. Res., Vol. 9, No. 8, pp. 439-46, 1997. Abstract.					
	Lambert, D.M., "Rationale and applications of lipids as prodrug carriers", European Journal of Pharmaceutical Sciences 11, Suppl. 2, pp. S15-S27, 2000.					
	Lukyanov, A. et al., "PE-PEG Micelles Demonstrate an Efficient Tumor Accumulation in Different Tumor Models in Mice", Controlled Release Society, 29 <sup>th</sup> Annual Meeting PROCEEDINGS, pp. 230-231, 2002.					
	Lukyanov, A. et al., "Polyethylene Glycol-Diacyllipid Micelles Demonstrate Increased Accumulation in Subcutaneous Tumors in Mice", Pharmaceutical Research, Vol. 19, No. 10, pp. 1424-1429, October 2002.					
	Torchilin, V. et al., "PEG-PE-Based Immunomicelles: New Family of Targeted Drug Carriers", Controlled Release Society, 29 <sup>th</sup> Annual Meeting PROCEEDINGS, pp. 497-498, 2002.					
	Torchilin, V. et al., "p-Nitrophenylcarbonyl-PEG-PE-liposomes: fast and simple attachment of specific ligands, including monoclonal antibodies, to distal ends of PEG chains via p-nitrophenylcarbonyl groups", Biochim. Biophys. Acta, Vol. 1511, No. 2, pp. 397-411, April 2, 2001. Abstract.					
	Torchilin, V. et al., "Polymer-lipid Micelles as Non-targeted and Targeted Pharmaceutical Carriers", Polymer Preprints, Vol. 43., No. 2, pp. 677-678, 2002.					
	Torchilin, V., "Structure and design of polymeric surfactant-based drug delivery systems", Journal of Controlled Release 73, pp. 137-172, 2001.					
	Torchilin, V. et al., "TAT peptide on the surface of liposomes affords their efficient intracellular delivery even at low temperature and in the presence of metabolic inhibitors", Proc. Natl. Acad. Sci. USA, Vol. 98, No. 15, pp. 8786-91, 2001.					
	Trubetskoy, V. et al., "Stable Polymeric Micelles: Lymphangiographic Contrast Media for Gamma Scintigraphy and Magnetic Resonance Imaging", Acad. Radiol, Vol. 3, No. 3, pp. 232-238, March 1996.					
EXAMINER	DATE CONSIDERED					
<b>*EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						